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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------|----------------------------------|-----------------------|---------------------|------------------|
| 10/524,701 | 02/16/2005 | Peter Emmanuel Petros | 4150/005 | 1385 |
| | 7590 06/16/200 CKMAN & REISMA | EXAMINER | | |
| 270 MADISON AVENUE | | | MASHACK, MARK F | |
| 8TH FLOOR NEW YORK, NY 10016-0601 | | | ART UNIT | PAPER NUMBER |
| | | | 3773 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 06/16/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|---|--|--|--|--|--|
| | 10/524,701 | PETROS, PETER EMMANUEL | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | MARK MASHACK | 3773 | | | | |
| The MAILING DATE of this communication app | ears on the cover sheet with the c | orrespondence address | | | | |
| Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period of - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>04 M</u> | av 2009 | | | | | |
| • | action is non-final. | | | | | |
| | | | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>17-28,30,32,33,35 and 52-55</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>17-28,30,32,33,35 and 52-55</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/o | r election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examine | r. | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11)☐ The oath or declaration is objected to by the Ex | aminer. Note the attached Office | Action or form PTO-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| See the attached detailed Office action for a list | or the certified copies not receive | a. | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary | (PTO-413) | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Da | ate | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4/1/2009</u> . | 5) Notice of Informal P 6) Other: | ателт Аррисатіоп | | | | |

DETAILED ACTION

This office action is in response to a communication dated 5/4/2009. Claims 17-28, 29, 32-33, 52-55 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/4/2009 has been entered.

Response to Arguments

- 2. Applicant's arguments filed 5/4/2009 have been fully considered but they are not persuasive.
- 3. Applicant argues that "the screw threads of Goble do not define prongs that are tapered nor prongs which diverge in a lengthwise direction while narrowing in cross section". Examiner disagrees. The threaded portion of Goble is considered prongs which are wider at the attached portion and become narrower at their free ends (FIG 21). Hence, they become narrower in cross-section which is essentially the definition of tapering. They also diverge from the longitudinal axis of the bone anchor.
- 4. Applicant argues that "none of the wings of any of the embodiments of Colleran has a cross section which narrows as the wing extends from the head". Examiner

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disagrees. Colleran depicts the prongs **219** taper as they extend form the head. Since they taper, they reduce in cross section, by definition.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **Claim 21** recites the limitation "the surface". There is insufficient antecedent basis for this limitation in the claim. Further clarification of "the surface" is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

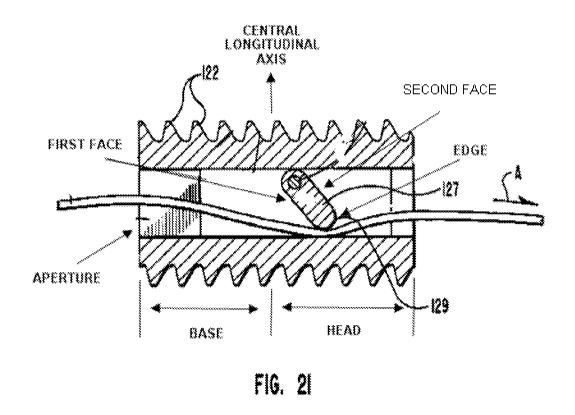
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 8. Claims 17-20, 22-26, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Goble et al. ("Goble" US 5,702,397).

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Goble disclose a tissue anchor. The tissue anchor comprises a base and a head (FIG 21). The head comprises tapered prongs 122 extending radially diverging in a lengthwise direction away from said head while narrowing in cross section (FIG 21). The base comprises an aperture and is associated with a locking element 127 that allows sliding of a filament through a space but restricts it from sliding the opposite direction (FIG 21 and Column 11, Lines 33-60). The locking element comprises two faces defining a convex arcuate edge (FIG 21). The space defined by the edge of the locking mechanism has a part annular configuration (due to arcuate edge and rounded edges) substantially corresponding to the cross section of the filamentary element (since it allows for the filament to pass) and substantially centrally across the central longitudinal axis of the anchor (FIG 21-22). The locking member inclined with respect to the base when the suture is present (FIG 21).

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9. Claims 17-20, 23-28, 30, 32-33, 52-54 is rejected under 35 U.S.C. 102(e) as being anticipated by Colleran et al. ("Colleran" US 2003/0088250).

Colleran disclose a tissue anchor comprising a base 230 and a head 215, 216, 219. Head comprises a barbed configuration (FIGs 4) with prongs 219a' comprising a tapered, pointed, resilient flexible tip (Paragraph 58). Said prongs 219a', b', c', d' are equidistant spacing around the central axis of the head (cross section 4E as shown in FIG 4D) and divergent away from the end of the head in the direction of the base (FIG 4A). The head comprises an aperture 235 and a locking member 250, 254 is inclined with respect to the base when the suture is present and allows the filamentary element to pass in one direction and impedes it in the opposite direction (FIGs 4 and Paragraph

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59-61). The locking member has a face in the one direction and a face in the opposite direction with an edge extending between the two which frictionally engages the suture (FIGs 4A-G and Paragraph 59-61).

Claim Rejections - 35 USC § 103

- 10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 11. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 12. Claims 18-21, 23-28, 30, 32-33, 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colleran in view of Pagedas et al. ("Pagedas" US 6,015,428).

Colleran discloses all of the claimed limitations including a locking member which is intended to allow the suture to pass in one direction and impedes it in the oppositie direction (FIG 4 and Paragraphs 59-61). If the previous rejection is not convincing concerning the locking member, Pagegas discloses a similar device with a

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plurality of embodiments (FIG 1-4 and 16-17) that are intended to provide a similar one-way locking member. The locking member has a face in each of the directions of the suture (FIG 1-4 and 16-17). One embodiment (FIG 1-4) depicts a locking element (three of the tongues 36) and an opposed edge (the remaining tongue 36) wherein the locking element comprises slots extending from the proximate face to atleast an intermediate portion across the surface of the filamentary element. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute one known element for another to yield predictable results. Given the teachings of **Pagedas**, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the locking element of **Colleran** for the locking element of **Pagedas**. Doing so would provide an improved means for enabling the passage of the suture through the aperture and prevent the withdrawal.

13. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colleran in view of Thompson (US 5,662,654).

Colleran discloses all of the claimed limitations except for the prongs each having a substantially cylindrical configuration. However, Thompson teaches of a similar suture anchor comprising substantially cylindrical barbs 141-148. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of

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Thompson, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the barbs of **Colleran** with the cylindrical deployable configuration of **Thompson**. Doing so would facilitate the insertion and retention of the suture anchor.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Mark Mashack/ Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/

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